



JC06 Rec'd PCT/PTO 27 MAY 2005

PCT

ATTORNEY DOCKET NO. 21105.0001U2
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
Bao et al.) Art Unit: Unassigned
International Application No. PCT/US03/16363) Examiner: Unassigned
International Filing Date May 22, 2003) Confirmation No. Unassigned
U.S. Application No. 10/518,872)
National Filing Date December 21, 2004)
For: RADIOLABELED COMPOUNDS AND)
LIPOSOMES AND THEIR METHOD OF)
MAKING AND USING SAME)

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INFORMATION DISCLOSURE STATEMENT

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NEEDLE & ROSENBERG, P.C.
Customer Number 23859

Sir:

Pursuant to the requirements of 37 C.F.R. § 1.56, submitted herewith on the accompanying Information Disclosure Statement List is a listing of documents known to Applicants and/or their attorneys. In accordance with 37 C.F.R. § 1.98(a)(2), copies of any cited U.S. patent or U.S. patent application publication documents are not enclosed. Copies of any cited foreign patent document and/or any non-patent publication are enclosed.

In accordance with the provisions of M.P.E.P. § 2001.06(b) and 37 C.F.R. § 1.98(b)(3), Applicants would like to bring to the attention of the Examiner the existence of the co-pending patent application(s) identified below, which were filed in the United States Patent and Trademark Office:

	<u>Application No.</u>	<u>Date Filed</u>	<u>Inventors</u>	<u>Attorney Docket No.</u>
1.	10/525,892	08/27/2004	Awasthi et al.	21105.0009U2

**ATTORNEY DOCKET NO. 21105.0001U2
International Application No. PCT/US03/16363**

This Information Disclosure Statement is believed to be filed in a timely manner pursuant to 37 C.F.R. § 1.97(b)(3), in that a first Office Action on the merits of the present patent application has not yet been mailed to Applicants.

Consideration of the cited documents and making the same of record in the prosecution of the above-referenced application are respectfully requested.

No fee is believed due; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

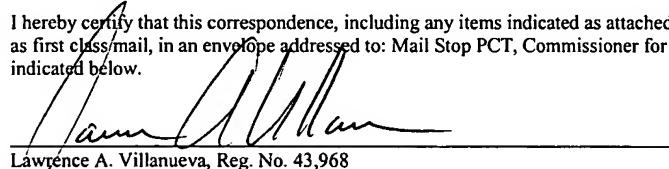
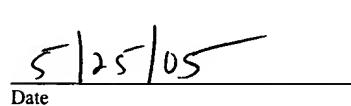
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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail, in an envelope addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.


Lawrence A. Villanueva, Reg. No. 43,968
Date

INFORMATION DISCLOSURE STATEMENT LIST (Use as many sheets as necessary)				Complete if Known			
				Application No.		10/518,872	
				Intl. Filing Date		PCT/US03/16363	
				First Named Inventor		Bao et al.	
				Group Art Unit		Unassigned	
				Examiner Name		Unassigned	
U.S. PATENT DOCUMENTS							
Examiner's Initials	Cite No.	Document No.	Date	Name	Class	Subclass	Filing Date (if appropriate)
	A1	6,477,329	11/05/02	Weng et al.	396	287	
	A2	6,320,017	11/20/01	Michial et al.	528	310	
	A3	6,316,028	11/13/01	Wong et al.	424	473	
	A4	6,316,024	11/13/01	Allen et al.	424	450	
	A5	6,294,191	09/25/01	Meers et al.	424	450	
	A6	6,258,378	07/10/01	Schneider et al.	424	450	
	A7	6,033,708	03/07/00	Kwasiborski et al.	424	450	
	A8	5,814,601	09/29/98	Winslow et al.	514	006	
	A9	5,770,560	06/23/98	Fischer et al.	514	006	
	A10	5,688,526	09/29/98	Winslow et al.	514	006	
	A11	5,676,971	10/14/97	Yoshioka et al.	424	450	
	A12	5,674,528	10/07/97	Ogata et al.	424	450	
	A13	5,665,380	09/09/97	Wallach et al.	424	450	
	A14	5,589,189	12/31/96	Moynihan et al.	424	450	
	A15	5,395,619	03/07/95	Zalipsky et al.	424	450	
	A16	5,158,760	10/27/92	Phillips	424	001.100	
	A17	5,143,713	09/01/92	Phillips et al.	424	1.21	
	A18	5,059,421	10/02/91	Laughrey et al.	424	417	
	A19	5,013,556	05/07/91	Woodle et al.	424	450	
	A20	4,911,929	03/27/90	Farmer et al.	264	4.3	
	A21	4,776,991	10/11/98	Farmer et al.	264	4.3	
	A22	4,310,505	01/12/82	Baldeschwieler	424	1.21	
	A23	2002/0095108	07/18/02	Tsuchida et al.	604	6.09	
FOREIGN PATENT DOCUMENTS							
Examiner's Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code	Date	Name		Translation Yes/No	
	A24	EP 0 572 049	12/01/93	Royal Free Hosp. School Med			
	A25	EP 0 354 855	02/14/90	Terumo Corp			
	A26	EP 0 220 797	05/06/87	Nikko Chemicals			
	A27	JP 4300838	10/23/92	Terumo Corp		Abstract	
	A28	JP 4005242	01/09/92	Terumo Corp		Abstract	
NON-PATENT DOCUMENTS							
Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)					
	A29	Ahl et al., "Enhancement of the in vivo circulation lifetime of L-alpha-distearylphosphatidylcholine liposomes: importance of liposomal aggregation versus complement opsonization." Biochim. Biophys. Acta. 1997 Oct 23; 329(2):370-82.					
	A30	Allen and Hansen, "Pharmacokinetics of stealth versus conventional liposomes: effect of dose." Biochim. Biophys. Acta. 1991 Sep 30; 1068(2):122-41.					

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			First Named Inventor	Bao et al.
			Group Art Unit	Unassigned
			Examiner Name	Unassigned
	A31	Allen et al., "Liposomes with prolonged circulation times: factors affecting uptake by reticuloendothelial and other tissues." <i>Biochim. Biophys. Acta.</i> 1989; 981:27-35. (Abstract)		
	A32	Awasthi et al., "Circulation and biodistribution profiles of long-circulating PEG-liposomes of various sizes in rabbits." <i>Int. J. Pharm.</i> 2003; 253:121-32.		
	A33	Awasthi et al., "Kinetics of liposome-encapsulated hemoglobin after 25% hypovolemic exchange transfusion." <i>International Journal of Pharmaceutics</i> 283 (2004) 53-62.		
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	A35	Banerjee et al. "Evolution of Tc-99m in Diagnostic Radiopharmaceuticals." <i>Seminars in Nuclear Medicine</i> , Vol. XXXI, No. 4: 260-2777 (October 2001)		
	A36	Blower et al. "Pentavalent rhenium-188 dimercaptosuccinic acid for targeted radiotherapy: synthesis and preliminary animal and human studies." <i>Eur J Nucl Med.</i> 25(6):613-21 (1998)		
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	A38	Carrion et al., "Preparation of long-circulating immunoliposomes using PEG-cholesterol conjugates: effect of the spacer arm between PEG and cholesterol on liposomal characteristics." <i>Chem. Phys. Lipids.</i> 2001 Nov; 113(1-2):97-110.		
	A39	Chen et al. "Efficacy of Re-188-labelled sulphur colloid on prolongation of survival time in melanoma-bearing animals." <i>Nuclear Medicine and Biology</i> 28 (2001); 835-844.		
	A40	Corbin et al. in "Preparation and Properties of Tripodal and Linear Tetradeятate N,S-Donor Ligands and Their Complexes Containing the MoO ₂ ²⁺ Core." <i>Inorganica Chimica Acta</i> , vol. 90, pp. 41-51 (1984)		
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	A42	Devine and Bradley, "The complement system in liposome clearance: Can complement deposition be inhibited?" <i>Adv. Drug Deliv. Rev.</i> 1998 Jun 8; 32(1-2):19-29.		
	A43	Drummond et al., "Optimizing liposomes for delivery of chemotherapeutic agents to solid tumors." <i>Pharmacol. Rev.</i> 1999 Dec; 51(4):691-743.		
	A44	Ehrhardt et al. "Reactor-Produced Radionuclides at the University of Missouri Research Reactor." <i>Appl. Radiat.</i> 49(4):295-297 (1998)		
	A45	Emfietzoglou et al. "An analytic dosimetry study for the use of radionucleotide-liposome conjugates in internal radiotherapy." <i>J. Nucl. Med.</i> 42(3):499-504 (2001)		
	A46	Fillion et al., "Encapsulation of DNA in negatively charged liposomes and inhibition of bacterial gene expression with fluid liposome-encapsulated antisense oligonucleotides." <i>Biochim. Biophys. Acta.</i> 2001 Nov 1; 1515(1):44-54.		
	A47	Frank, <i>Physiological Data of Laboratory Animals</i> , in "Handbook of Laboratory Animal Science" (Melby EC, Jr. ed) pp 23-64, CRC Press, Boca Raton, FL.		
	A48	Frost & Sullivan, "Future of nuclear medicine, part 3: Assessment of the U.S. therapeutic radiopharmaceuticals market (2001-2020)." <i>J Nuc Med.</i> 39(7):14N-27N (1998)		

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INFORMATION DISCLOSURE STATEMENT LIST (Use as many sheets as necessary)			Complete if Known
			Application No.
	A49	Gabizon and Papahadjoulos, "The role of surface charge and hydrophilic groups on liposome clearance in vivo." <i>Biochim. Biophys. Acta</i> 1992; 1103:94-100	10/518,872
	A50	Goins and Phillips, "The Use of scintigraphic imaging as a tool in the development of liposome formulation." <i>Prog. Lipid Res.</i> 2001; 40:95-123.	PCT/US03/16363
	A51	Goins et al., "Blood-pool imaging using technetium-99m-labeled liposomes." <i>J. Nucl. Med.</i> 1996 Aug; 37(8):1374-9.	Bao et al.
	A52	Goins et al., "Physiological responses, organ distribution, and circulation kinetics in anesthetized rats after hypovolemic exchange transfusion with technetium-99m-labeled liposome-encapsulated hemoglobin." <i>Shock.</i> 1995 Aug; 4(2):121-30.	Unassigned
	A53	Goram and Richmond, "Pegylated liposomal doxorubicin: Tolerability and toxicity." <i>Pharmacotherapy</i> 2001; 21:751-63.	Unassigned
	A54	Grant N00014-00-1-0793 awarded by the Office of Naval Research	
	A55	Gregoriadis, "Fate of liposomes in vivo and its control: A historical perspective." in <i>Stealth Liposomes</i> (Lasic DD and Martin F eds) pp 7-12, CRC Press, Boca Raton, FL (1995).	
	A56	Hafeli et al. "A lipophilic complex with ¹⁸⁶ Re/ ¹⁸⁸ Re incorporated in liposomes suitable for radiotherapy." <i>Nuc. Med. Biol.</i> 18: 449-454 (1991)	
	A57	Harashima et al., "Identification of proteins mediating cleatance of liposomes using a liver perfusion system." <i>Adv. Drug Deliv. Rev.</i> 1998; 32:61-79.	
	A58	Hashimoto et al. "Rhenium Complexes Labeled with ¹⁸⁶ Rh/ ¹⁸⁸ Rh for Nuclear Medicine." <i>Curr. Chem.</i> 176:275-291 (1996)	
	A59	Hope et al., "Production of large unilamellar vesicles by a rapid extension procedure, characterization of size distribution, trapped volume & ability to maintain membrane potential." <i>Biochim Biophys. Acta.</i> 812:55-65, (1985)	
	A60	Ishiwata et al. "Polyethyleneglycol derivatives of cholesterol reduces binding step of liposome uptake by murine macrophage-like cell line J774 and human heptoma cell line Hep62" <i>Chem. Pharm. Bull.</i> 1988, 46:1907-13.	
	A61	Kim et al., "Pharmacodynamics of insulin in polyethylene glycol-coated liposomes." <i>Int. J. Pharm.</i> 1999 Mar 25; 180(1):75-81.	
	A62	Klibanov et al., "Activity of amphiphatic poly(ethylene glycol) 5000 to prolong the circulation time of liposomes depends on the liposome size and is unfavorable for immunoliposome binding to target." <i>Biochim. Biophys. Acta</i> 1991; 1062:142-8	
	A63	Knapp et al. "Availability of Rhenium-188 from the Alumina-Based Tungsten-188/Rhenium-188 Generator for Preparation of Rhenium-188-Labeled Radiopharmaceuticals for Cancer Treatment." <i>Anticancer Research</i> 17:1783-1796 (1997)	
	A64	Knapp et al. "Processing of Reactor-produced 188W for Fabrication of Clinical Scale Alumina-based 188W/188Re Generators." <i>Appl. Radiat. Isot.</i> 45(12):1123-1128 (1994)	
	A65	Knapp et al. "The continuing important role of radionuclide generator systems for nuclear medicine." <i>Eur. J. Nucl. Med.</i> 21:151-165 (1994)	
	A66	Kniess et al. "Cyclic voltammetric investigations on oxorhenium(v) complexes of the "3+1" type" <i>Forchungszent. Rossendorf FZR-122:136-9 (1996). Abstract</i>	
	A67	Kostarelos and Emfietzoglou, "Liposomes as carriers of radionucleotides: from image to therapy." <i>J. Liposome Res.</i> 9(4):429-460 (1999)	

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INFORMATION DISCLOSURE STATEMENT LIST (Use as many sheets as necessary)			Complete if Known
	A68	Kostarelos et al. "Tissue dosimetry of liposome-radionuclide complexes for internal radiotherapy: toward liposome-targeted therapeutic radiopharmaceuticals" Anticancer Res. 20:3339-46 (2000)	Application No. 10/518,872
	A69	Lasic, "Liposomes." Science and Medicine, May/June (1996) 34-43.	Intl. Filing Date PCT/US03/16363
	A70	Lasic and Martin, eds., Stealth Liposomes. CRC Press, Boca Raton, FL (1995). Chapter 1	First Named Inventor Bao et al.
	A71	Laverman et al., "Preclinical and clinical evidence for disappearance of long-circulating characteristics of polyethylene glycol liposomes at low lipid dose." J. Pharmacol. Exp. Ther. 2000; 293:996-1001.	Group Art Unit Unassigned
	A72	Levchenko et al., "Liposome clearance in mice: the effect of a separate and combined presence of surface charge and polymer coating." Int. J. Pharm. 2002 Jun 20; 240(1-2):95-102.	Examiner Name Unassigned
	A73	Li et al. "Rhenium-188 HEDP to treat painful bone metastases." Clin Nucl Med. 26(11):919-22. (2001)	
	A74	Litzinger and Huang "Amphiphatic poly(ethylene glycol) 5000-stabilized dioleoylphosphatidylethanolamine liposomes accumulate in spleen." Biochim Biophys Acta. 1127(3):249-54 (1992)	
	A75	Liu et al., "Role of liposome size and RES blockade in controlling biodistribution and tumor uptake of GM1-containing liposomes." Biochim. Biophys. Acta 1992; 1104:95-101.	
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	A77	Mastostamatis et al. "Tridentate ligands containing the SNS donor atom set as a novel backbone or the development of technetium brain-imaging agents." J Med Chem. 37:3212-3218 (1994)	
	A78	Matsuoka, "Determination of methemoglobin and carboxyhemoglobin in blood by rapid colorimetry." Biol. Pharm. Bull. 1997 Nov; 20(11):1208-11.	
	A79	Maurer-Spurej et al. "Factors influencing uptake and retention of amino-containing drugs in large unilamellar vesicles exhibiting transmembrane pH gradients." Biochimica Biophysica Acta 1416:1-10 (1999)	
	A80	Mayer et al., "Uptake of antineoplastic agents into large unilamellar vesicles in response to a membrane potential." Biochim. Biophys. Acta. 1985 Jun 27; 816(2):294-302.	
	A81	Mayer et al., "Vesicles of variable sizes produced by a rapid extrusion procedure." Biochim Biophys Acta. 1986 Jun 13; 858(1):161-8 (1986)	
	A82	Mayhew et al. "High-pressure continuous-flow system for drug entrapment in liposomes." Methods Enzymol. 149:64-77 (1987)	
	A83	McCready and Cornes, "The potential of intratumoural unsealed radioactive source therapy." Eur J Nuc Med. 28:567-569 (2001)	
	A84	Mease et al. "Newer methods of labeling diagnostic agents with Tc-99m." Seminars in Nuclear Medicine, Vol. XXXI, No. 4:278-285 (October 2001)	
	A85	Miller et al., "Liposome-cell interactions in vitro: effect of liposome surface charge on the binding and endocytosis of conventional and sterically stabilized liposomes." Biochemistry. 1998 Sep 15; 37(37):12875-83.	

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	A86	Moreira et al., "Use of the post-insertion technique to insert peptide ligands into pre-formed stealth liposomes with retention of binding activity and cytotoxicity." Pharm. Res. 2002; 19(3):265-9.	Application No. 10/518,872
	A87	New, in Liposomes : A Practical Approach, New (ed), Oxford University Press, NY, 33-104 (1990)	Intl. Filing Date PCT/US03/16363
	A88	Nicholas et al., "Effect of grafted polyethylene glycol (PEG) on the size, encapsulation efficiency and permeability of vesicles." Biochim. Biophys. Acta. 2000 Jan 15; 1463(1):167-78.	First Named Inventor Bao et al.
	A89	Oja et al., "Influence of dose on liposome clearance: critical role of blood proteins." Biochim. Biophys. Acta 1996; 1281:31-7.	Group Art Unit Unassigned
	A90	Papadopoulos et al. "Syn-anti isomerism in a mixed-ligand oxorhenium complex ReO[SN(R)S][S]." Inorg Chem 35: 7377-7383 (1996)	Examiner Name Unassigned
	A91	Petty, Research Techniques in the Rats. Charles C. Thomas, Springfield, IL (1982).	
	A92	Phillips and Goins in Handbook of targeted delivery of imaging agents. Chapter 10, CRC Press, Boca Raton, FL (1995)	
	A93	Phillips et al. "A simple method for producing a technecium-99m-labeled liposome, which is stable in vivo." Nuc. Med Biol. 19:539-547 (1992)	
	A94	Phillips et al. "Development of Liposome Encapsulated Hemoglobin (LEH) and Studies of Hemorrhagic Shock by Use of Imaging Studies with Oxygen-15 and Other Radiotracers."	
	A95	Phillips et al., "Polyethylene glycol-modified liposome-encapsulated hemoglobin: a long circulating red cell substitute." J. Pharmacol. Exp. Ther. 1999 Feb; 288(2):665-70.	
	A96	Phillips, "Delivery of gamma-imaging agents by liposomes." Adv. Drug Deliv. Rev. 1999; 37:13-32.	
	A97	Proctor, "Blood substitutes and experimental models of trauma." J Trauma. 2003 May; 54(5 Suppl):S106-9.	
	A98	Qaim, "Production of High Purity ^{94m} Tc for Postitron Emission Tomography Studies." Nuclear Medicine & Biology, Vol. 27, pp. 323-328, 2000.	
	A99	Rabinovici et al., "Liposome-encapsulated hemoglobin: an oxygen-carrying fluid." Circ Shock. 1990 Sep; 32(1):1-17.	
	A100	Reiss, "Oxygen carriers ("blood substitutes")--raison d'etre, chemistry, and some physiology." Chem Rev. 2001 Sep; 101(9):2797-920.	
	A101	Roberts and Bratton, "Colloid volume expanders. Problems, pitfalls and possibilities." Drugs. 1998 May; 55(5):612-30.	
	A102	Rudolph, "Encapsulation of Hemoglobin in Liposomes," in Blood substitutes: Physiological Basis of Efficacy, Intaglietta M. ed., pp 90-104, Birkhauser, Boston, 1995.	
	A103	Sakai et al., "Physical properties of hemoglobin vesicles as red cell substitutes." Biotechnol. Prog. 1996 Jan-Feb; 12(1):119-25.	
	A104	Sakai et al., "Poly(ethylene glycol)-conjugation and deoxygenation enable long-term preservation of hemoglobin-vesicles as oxygen carriers in a liquid state." Bioconjug. Chem. 2000 May-Jun; 11(3):425-32.	
	A105	Sakai et al., "Surface modification of hemoglobin vesicles with poly(ethylene glycol) and effects on aggregation, viscosity, and blood flow during 90% exchange transfusion in anesthetized rats." Bioconjug Chem. 1997 Jan-Feb; 8(1):23-30.	
	A106	Semple et al. "Interactions of liposomes and lipid-based carrier systems with blood proteins: Relation to clearance behaviour in vivo." Adv. Drug Deliv. Rev. 1998 Jun 8; 32(1-2):3-17.	

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	A107	Shimada et al., "Determination of incorporated amounts of poly(ethylene glycol)-derivatized lipids in liposomes for the physicochemical characterization of stealth liposomes." Int. J. Pharm. 2000 Aug 10; 203(1-2):255-63.	
	A108	Solanki et al. "Seven-hour stabilization of 99mTc-exametazime (HMPAO) for cerebral perfusion." Nucl Med Commun. 19:567-572 (1998)	
	A109	Sou et al., "Poly(ethylene glycol)-modification of the phospholipid vesicles by using the spontaneous incorporation of poly(ethylene glycol)-lipid into the vesicles." Bioconjug Chem. 2000 May-Jun; 11(3):372-9.	
	A110	Squires, "Artificial blood." Science. 2002 Feb 8; 295(5557):1002-5.	
	A111	Srivastava et al. "Recent advances in radionuclide therapy." Seminars In Nuclear Medicine, Vol. XXXI, No. 4: 330-341, (October 2001)	
	A112	Sriwongsitanont and Ueno, "Physicochemical properties of PEG-grafted liposomes." Chem. Pharm. Bull. (Tokyo). 2002 Sep; 50(9):1238-44.	
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	A115	Szebeni, "Complement Activation-Related Pseudoallergy Caused by Liposomes, Micellar Carriers of Intravenous Drugs, and Radiocontrast Agents." Critical Reviews in Therapeutic Drug Carrier Systems, 18(6):567-606 (2001).	
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	A117	Takeoka et al., "Layer-controlled hemoglobin vesicles by interaction of hemoglobin with a phospholipid assembly." Langmuir 1996; 12:1755-9.	
	A118	Thakur et al., "Indium-LLL labeled platelets: studies on preparation and evaluation of in vitro and in vivo functions." Thromb. Res. 1976 Oct; 9(4):345-57.	
	A119	Thompson, "Drug Bioscreening: Drug Evaluation Techniques in Pharmacology," VCH Publishers, New York, 1990; 321-339.	
	A120	Tomita et al., "A simple spectrophotometric method for determination of met-hemoglobin in dilute solution." J. Nara. Med. Assoc. 1968; 19:1-6.	
	A121	Torchilin and Papisov, "Why do polyethylene glycol-coated liposomes circulate so long?" J. Liposome Res. 1994; 4:725-739.	
	A122	Uster et al., "Insertion of poly(ethylene glycol) derivatized phospholipid into pre-formed liposomes results in prolonged in vivo circulation time." FEBS Lett. 1996 May 20; 386(2-3):243-6.	
	A123	Vertut-Doi et al., "Binding and uptake of liposomes containing a poly(ethylene glycol) derivative of cholesterol (stealth liposomes) by the macrophage cell line J774: influence of PEG content and its molecular weight." Biochim Biophys Acta. 1996 Jan 12; 1278(1):19-28.	
	A124	Volkert et al. "Technetium-99m chelates as radiopharmaceuticals." Curr. Chem. 176:125-148 (1996)	
	A125	Walde and Ichikawa, "Enzymes inside lipid vesicles: preparation, reactivity and applications." Biomol. Eng. 2001 Oct 31; 18(4):143-77.	

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		Group Art Unit	Unassigned
		Examiner Name	Unassigned
A126	Webb et al., "Comparison of different hydrophobic anchors conjugated to poly(ethylene glycol): effects on the pharmacokinetics of liposomal vincristine." Biochim Biophys Acta. 1998 Jul 17; 1372(2):272-82.		
A127	Yuda et al., "Prolongation of liposome circulation time by various derivatives of polyethyleneglycols." Biol Pharm Bull. 1996 Oct; 19(10):1347-51.		

Examiner Signature:	Date Considered:
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	